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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,531	06/30/2003	Subramanian S. Venkatraman	ARC 2869 N1	2177

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EXAMINER	
GHALI, ISIS A D	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 07/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/611,531	VENKATRAMAN ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-53 is/are pending in the application.

4a) Of the above claim(s) 1-11 and 34-53 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 12-33 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6.3.03; 4/25/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' IDS filed 06/30/03; preliminary amendment filed 10/07/2004; and IDS filed 04/25/2005.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-11, 34-53, drawn to matrix material and method of its making, classified in class 424, subclass 484.

   II. Claims 12-33, drawn to transdermal drug delivery device, classified in class 424, subclass 449.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as forming blood bags, IV tubing and catheters as disclosed by US 4,523,005 and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious

variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. During a telephone conversation with Ms. Angela Nawneri on July 14, 2005 a provisional election was made with traverse to prosecute the invention of Group II, claims 12-33. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-11 and 34-53 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 12-33 are pending and included in the prosecution.

Specification

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 12-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are confusing because claim 12 recites that the polyurethane polymer has a process temperature of less than about 150 ^{0}C while applicants' disclosure in example 1 showed this temperature is the temperature at which the mixture of the drug, enhancer and the polyurethane polymer is melt blended. Clarification is requested.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 12-15, 20, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,010,715 ('715).

US '715 teaches a transdermal drug delivery device for controlled release of active agent to the skin or mucosa comprising laminate comprising backing layer, matrix layer formed from melt blend of the active agent and a polyether polyurethane polymer, and means for affixing the laminate to the skin or mucosa (abstract; col.5, lines 10-25). The matrix comprises active agent such as narcotic analgesic in an amount of 2-10% and enhancer (col.14, line 18; col.20, lines 33, 49-51). The means for affixing the laminate to the skin is an adhesive layer that can be acrylate adhesive (col.17, lines 14-16, 39-41).

US '715 does not teach the exact process temperature as claimed; however, the reference teach that the temperature of the melt blending should be a temperature at which the active agent is stable (abstract).

US '923 teaches a transdermal plaster comprising hot melt adhesive matrix comprising melt blend of polyurethane and 0.1 to 10% of an active agent, wherein the adhesive has processing temperature between 60 ^{0}C and 100 ^{0}C and melt the solidify while forming adhesive and cohesive forces and the cohesive forces generally decrease with decreasing the softening temperature of the hot melt adhesive (abstract; col.2, lines 25-30, 37, 62-67; col.7, line 14). The plaster comprises backing layer and adhesive layer to fix the plaster to the skin (col.4, lines 65-67; col.5, lines 1-3). The thickness of the adhesive layer is 30 to 250 μm (col.5, lines 53-54).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal drug delivery device that has matrix formed of melt blend of polyurethane ether and active agent as disclosed by US '715, and use a temperature between 60 ^{0}C and 100 ^{0}C to melt blend the drug and the adhesive as disclosed by US '923, motivated by the teaching of US '923 that decreasing the melt temperature generally decreases the cohesive forces of the adhesive with reasonable expectation of having transdermal delivery device having a matrix formed of melt blend of polyurethane ether and a drug that is processed at a temperature between 60 ^{0}C and 100 ^{0}C to achieve the desired cohesiveness and adhesiveness of the melt when solidify.

12. Claims 16-19 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '715 in view of US '923 as applied to claim12-15 above, and further in view of US Re 32,991 ('991).

The combined teaching of US '715 and US '023 are discussed above, however, combination does not teach what the polyurethane is formed from.

US '991 teaches polymer matrix comprising blend of active agent and a polyurethane elastomer TECOFLEX, which is the polyether polyurethane claimed by applicants formed by the same reaction process (abstract; col.2, lines 63-68; col.3, lines 66-68; col.6, line 46; col.7, lines 49, 67). The drug forms 4% of the matrix (col.7, line 48). The modulus of the TECOFLEX is expected to be the same as the modulus of the polyurethane matrix claimed in claim 33. The elastomer is strong yet flexible to conform to the shape of the site of application and have suitable viscosity that facilitates admixture with the drugs to form homogenous blend (col.2, lines 5-26).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal drug delivery device that has matrix formed of melt blend of polyurethane ether and active agent as disclosed by US '715 in combination with US '923, and select TECOFLEX as the polyurethane ether to form the matrix containing drug as disclosed by US '991, motivated by the teaching of US '991 that TECOFLEX is strong yet flexible to conform to the shape of the site of application and have suitable viscosity that facilitates admixture with the drugs to form homogenous blend, with reasonable expectation of having a transdermal device that deliver drugs

from melt blend matrix containing TECOFLEX and drug that is homogenously includes the drug and conforms comfortable to the skin.

13. Claims 21, 23-29, 31, 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '715 in view of US '923 as applied to claims 12-15, 20, 22 above, and further in view of US '6,139,866 ('866).

The teachings of US '715 and US '923 are discussed above. However, the references do not teach specifically fentanyl as the drug to be delivered from the melt blended matrix, or the specific permeation enhancers.

US '866 teaches percutaneous formulation to deliver fentanyl wherein the formulation is stable and has little irritation to the skin and excellent in percutaneous permeation of fentanyl (abstract). The formulation comprises 0.05-20% of fentanyl, 0.1-98% of PSA, and 0.01-20% of permeation enhancer such as glycerol monolaurate (col.1, lines 65-67; col.2, lines 1-2; col.4, lines 28-31, 37-39).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal drug delivery device that has matrix formed of melt blend of polyurethane ether and active agent as disclosed by US '715 in combination with US '923, and replace the narcotic analgesic disclosed by US '715 by fentanyl and the enhancer by glycerol monolaurate as disclosed by US '866, motivated by the teaching of US '866 that such a formulation is stable and has little irritation to the skin and excellent in percutaneous permeation of fentanyl, with reasonable expectation of having a transdermal device that deliver fentanyl from a melt blend matrix comprising

polyurethane ether and glycerol monolaurate that has excellent permeation to fentanyl without skin irritation.

14. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '715 in view of US '923 and US '866 as applied to claims 12-15, 20-29, and 31-33 above, and further in view of US 5,225,199 ('199).

The combination of US '715 with US '923 and US '866 does not teach lauryl pyroglutamate as a permeation enhancer.

US '199 teaches plaster for transdermal drug delivery device to deliver active agents such as narcotic analgesics, wherein the plaster comprises polyurethane, drug and permeation enhancer such as lauryl pyroglutamate (abstract; col.7, lines 15-17, 22-24; col.14, lines 50, 62). The plaster enables the absorption of effective amounts of a drug with extremely reduced skin rash with no breakage or peeling of the skin (col.2, lines 22-27).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal drug delivery device that has matrix formed of melt blend of polyurethane ether, fentanyl and enhancer as disclosed by US '715 in combination with US '923 and US '866, and replace the enhancer by lauryl pyroglutamate disclosed by US '199, motivated by the teaching of US '199 that the plaster comprising lauryl pyroglutamate enables the absorption of effective amounts of a drug with extremely reduced skin rash with no breakage or peeling of the skin, with reasonable expectation of having a transdermal device that deliver fentanyl from a melt

blend matrix comprising polyurethane ether and lauryl pyroglutamate that has excellent permeation to fentanyl with minimal skin breakage or rash.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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PATENT EXAMINER